

REMARKS

Applicant respectfully requests reconsideration of this application in view of the amendments and remarks made herein.

Claims 1- 45 are canceled. New claims 46-65 have been added, as discussed in detail herein. No new matter has been added by these new claims. Applicant respectfully submits that the present new claims are drawn to the previously elected groups and are supported by the original disclosure of this application. As such, no new matter has been added by these claims.

Attorneys for Applicant wish to take this opportunity to thank the Examiner for taking the time to interview this case on April 5, 2005.

Priority

Applicant submits herewith a certified copy of the correct foreign priority application with a petition and the required fee.

Claim Rejections

1. 35 U.S.C. § 112, first paragraph

a. New Matter

Claims 1, 29, 33-34 and 38 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Claim 1 recites "with the proviso that the specific cells do not consist of pollen cells." The Examiner maintains that such language is considered to be new matter.

Applicant respectfully disagrees with the Examiner's rejection. However, since Applicant has canceled claimed 1, this rejection is moot.

b. Claims are Enabled to Person of Skill in the Art to Practice the Invention

The Examiner rejected claims 40, 42 and 44-45 as not enabled for a method that employs any part of the coding sequence of a mature PAP coding sequence that is 70% homologous to SEQ ID NO: 3, 5 or 7 and a sequence at least 80% homologous to SEQ ID NO: 4, 6, or 8 and retaining ribosome inactivating activity.

The test for enablement is whether one reasonably skilled in the art could make or use the invention, without undue experimentation, from the disclosure in the patent coupled with information known in the art at the time the patent application was filed. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).

Applicant has canceled the rejected claims and replaced them with new claims which no longer contain language regarding the degree of homology. The new claims recite sequences that bind under stringent conditions to SEQ ID NO: 3, 5 or 7 **and** encode a pokeweed antiviral protein that is capable of inducing cell death. The newly added claims are enabled as they possess both a structural and functional element and, as such, enable one of skill in the art to practice the invention.

Applicant maintains that support for the claimed invention can be found on p. 11, line 16, through p. 12, line 10 of the specification, which discloses stringent hybridization conditions that may be used to isolate additional sequences encoding a pokeweed antiviral protein having ribosome inactivating activity that, by virtue of that activity, is capable of inducing cell death. Furthermore, the working examples of the specification describe an assay based on GUS protein synthesis for confirmation that the isolated nucleic acid molecule encodes a protein with ribosome inactivating activity. Applicant maintains that given that the specification discloses SEQ ID NO.: 3, 5 and 7 and stringent hybridization conditions, coupled with working examples that describe assays for detecting ribosome inactivating activity, undue experimentation would not be required by one of ordinary skill in the art to develop the methods encompassed by the claims for inducing cell death in specific cells of a plant.

Accordingly, applicant respectfully submits that these and all pending claims satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph. Applicant respectfully requests that this ground of rejection be withdrawn.

b. Invention is Adequately Described in the Specification

The Examiner rejected claims 1-4, 22-23, 28-29, 31, 33-34, 36-38, 40 42 and 44-45 as not being adequately described in the specification in such a way to convey to one skilled in the art, at the time the application was filed, that the Applicant had possession of the claimed invention. According to the Examiner, the Applicant has not provided evidence showing that all sequences having at least 70% homology to SEQ ID NO: 3, 5 or 7 and a sequence at least 80% homologous to SEQ ID NO: 4, 6, or 8 retain functional activity as claimed in the claimed methods.

Factors to be considered in determining whether there is sufficient written description include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function and method of making the claimed invention. Where the specification discloses relevant identifying characteristics, i.e., physical, chemical and/or functional characteristics, sufficient to allow a skilled artisan to recognize that the applicant was in possession of the claimed invention, a rejection for lack of written description under Section 112, first paragraph, cannot be maintained. *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002).

Applicant has canceled the rejected claims and replaced them with new claims that no longer contain language regarding the degree of homology. The new claims recite sequences that bind under stringent conditions to SEQ ID NO: 3, 5 or 7 **and** encode a pokeweed antiviral protein that is capable of inducing cell death.

As indicated above, support for the claimed invention can be found on p. 11, line 16, through p. 12, line 10, of the specification which discloses stringent hybridization conditions that may be used to isolate additional sequences encoding a pokeweed antiviral protein having ribosome inactivating activity which, by virtue of that activity, is capable of inducing cell death. Furthermore, the working examples of the specification describe an assay based on GUS protein synthesis for confirmation that the isolated nucleic acid molecule encodes a protein with ribosome inactivating activity.

Moreover, it should be noted that as early as 1992, it was known that type I ribosome inactivating proteins “existed with structural similarities and apparently identical function in plants belonging to taxonomically unrelated families.” (*See, Stripe, et al.*, 1992, *Biotechnology* 10:405; p. 405, right col.; attached herewith as Exhibit A). Given this knowledge, it would not be unexpected that nucleic acid molecules binding under stringent conditions to SEQ ID NO: 3, 5 or 7 would encode a protein with ribosome inactivating activity.

Applicant submits that, given the teachings of the specification of both structural and functional features of pokeweed proteins encompassed by the claims, a sufficient written description has been provided. Therefore, the rejection is erroneous and Applicant respectfully requests withdrawal of the rejections of these and all pending claims under 35 U.S.C. § 112, first paragraph.

2. 35 U.S.C. § 112, Second Paragraph

Claims 1-4, 22-24, 28-29, 31, 33-34, 36-45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. According to the Examiner, it is unclear what is encompassed by and how to stimulate the “natural development” of a plant. It is also unclear whether it is the plant or the promoter that is responsive to the pathogen or chemical. Further it is unclear what is encompassed by “changes in flower morphology” and “seed release.”

Applicant has canceled the rejected claims and replaced them with new claims that more particularly point out and distinctly claim the subject matter that applicant regards as the invention. In particular, the claims have been amended to replace the phrase “stimulating natural development” with the phrase “allowing natural development.” The claims have also been amended to indicate that the inducible promoter “induces expression of the mature pokeweed antiviral protein in said specific cells upon exposing of said plant to a pathogen or a chemical or allowing natural development.” Furthermore, the phrases “changes in flower morphology” and “seed release” have been deleted from the claims.

Claims 1-4, 22, 36-37, 39-45 were rejected as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. The new claims indicate that the inducible promoter controls the expression of mature pokeweed proteins and that the expression of said protein results in cell death.

Claims 28, 33, and 39 were alleged to be indefinite in the recitation of “promoter is induced in...cells adjacent to...” because promoters for adjacent cells as listed in the claims are unknown to one of ordinary skill in the art, and are not defined in the specification. To expedite the allowance of claims, Applicant has amended the claims to remove any reference to induction in adjacent cells. Applicant reserves the right to prosecute such subject matter in later filed applications.

Claim 31 is said by the Examiner to be indefinite in the recitation of “DNA isolate of a chimaeric gene of claim 4” because claim 4 is drawn to a method rather than a chimeric gene. Claim 31 has been canceled and replaced with new claim 56 which no longer depends upon a method claim.

Applicant asserts that all pending claims satisfy the requirements 35 U.S.C. § 112, second paragraph.

3. Claims are Not Obvious Over Cited Art

Claims 1-4, 22-24, 28-29, 31 and 33-38 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Kanieswski *et al.* (U.S. Patent No. 6,015,940, hereafter “Kanieswski”) in view of Baszczynski *et al.* (U.S. Patent No. 5,756,324, hereinafter “Baszczynski”).

The Examiner contends that it would have been obvious to one of ordinary skill in the art to use the method of transforming a plant with pokeweed antiviral protein encoding DNA to induce viral resistance as taught by Kanieswski, and to modify that method by incorporating any other PAP-encoding DNA sequence with a cell specific regulatory element to induce cell-specific necrosis. The Examiner notes that one would have been motivated to do so because PAPs are known to induce necrotic effects (protein synthesis inhibiting activities in plants).

Applicant has amended the claims to encompass “a method of **inducing cell death** in specific cells of a plant.” The claimed method is based on the inducible expression of the cytotoxic pokeweed antiviral protein in specific cells of a plant. In contrast, Kanieswski teaches using pokeweed antiviral protein expression to render a transgenic plant resistant to viral infection. There is absolutely no teaching or suggestion to use pokeweed antiviral protein to selectively cause **cell death** in the transgenic plant's own parts. In fact, the purpose of generating such resistance to viral infection, as taught by Kanieswski, is to preserve the vitality of the cells.

Baszczynski discloses a regulatory element that confers microspore – specificity to gene expression and to using such regulatory element to produce transgenic plants in which microspore function is disrupted; and the use of a microspore-specific regulatory element to protect against viral and insect pests by disrupting the function of the virus or by encoding an insecticidal toxin thereby conferring disease resistance. Although Baszczynski discloses methods for disrupting microspore function, the reference fails to teach or suggest that such disruption leads to cell death of said microspores. With regard, to protection against viral and insect pests, the method of Baszczynski is targeted to disrupt the function of a virus or insect, rather than target plant cell death.

Thus, neither Kanieswski nor Baszczynski, separately or in combination, teach or suggest the use of pokeweed antiviral protein to selectively cause **cell death** in the transgenic plant. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection. Applicant asserts that all pending claims satisfy the requirements of 35 U.S.C. § 103(a).

CONCLUSION

Applicant respectfully submits that all pending claims are presently in condition for allowance. Prompt and favorable reconsideration and allowance of all pending claims is respectfully requested.

The Commissioner is authorized to charge any fees relevant to this filing to Deposit Account No. 11-0600. The Examiner is invited to contact the undersigned to discuss any matter in this application.

Respectfully submitted,
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